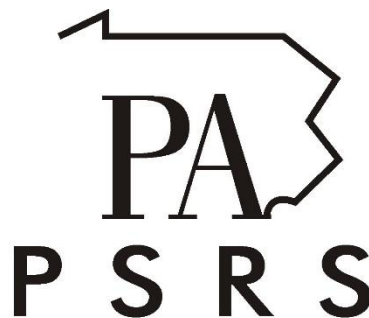

PA-PSRS Automated Data Interface XML Specifications

Part 1 of 3 – System Description



Pennsylvania Patient Safety Reporting System

Supports Schema Version 8.1

October 1, 2021

Production Implementation 1/1/2022

All information provided regarding the PA-PSRS Data Interface specifications, which information includes but is not limited to information regarding the data structure and processing logic of the PA-PSRS system, is owned exclusively by the Pennsylvania Patient Safety Authority. This information may be used only in connection with, and solely for the purpose of, the development of an interface between the PA-PSRS system and an internal reporting system at a medical facility that is: 1) physically located in the Commonwealth of Pennsylvania and, 2) subject to the reporting requirements of Act 13.

Document History

Version	Date Last Updated By	Change Description
6.0	March 1, 2006 by Electronic Data Systems – HLW	Original document.
6.1	May 26, 2006 by Electronic Data Systems – JMC	Modified version number to match additional documents (part 2, part 3).
6.2	August 21, 2006 by Electronic Data Systems – JMC	Modified version number to match additional documents (part 2, part 3).
6.3	August 15, 2007 by Electronic Data Systems – CLP	Changed Data Report File and Acknowledge Report File format from YYCCMMDD to YYYYMMDD (pages 14 & 15)
6.4	September 18, 2007 by Electronic Data Systems – CLP	Modified Section 4.6 Declaring the XML documents (page 13) Modified Section 3.4 System Setup (page 9) Modified Section 3.5 Security (page 10)
6.5	March 17, 2008 by Electronic Data Systems – BJK/CLP	Made reference to SSL transfer more clear for readers
Supports Schema Version 6.5	January 12, 2015 by HP	Changed version number to reflect the schema the document supports. Reworded “Based on harm score selected, no response is needed” to “Based on harm score, no response is required but encouraged”. Updated diagrams.
Supports Schema Version 7.0	DXC Technology April 30, 2017	Upgraded document to current version of Microsoft Word. No changes to this document are necessary for version 7.0
Supports Schema Version 7.0	DXC Technology August 10, 2020	Removed Patient Safety Authority address from header.
Supports Schema Version 8.0	Gainwell Technologies July 22, 2021	Updated sections 3.2, 3.4.1 and 3.5.1 to remove reference to SSL
Supports Schema Version 8.1	Gainwell Technologies October 1, 2021	Updated footer to Support Schema Version 8.1 to match Part 2 and Part 3 specifications.

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1 Introduction

The Patient Safety Authority has enhanced the Patient Safety Reporting System (PA-PSRS) to allow Pennsylvania medical facilities the ability to submit reports directly from their existing internal reporting (IR) system. An electronic interface provides a streamlined and efficient submission process by eliminating the duplicate effort of entering reports into an IR system and then into PA-PSRS. PA-PSRS has been modified to accept batched reports in an XML format that conforms to the published interface standards set forth in this document.

For a facility to transmit reports electronically to the Automated Data Interface system modifications are required to the facility's internal reporting system. The facility's IR system must be modified to gather reportable events, defined under Act 13 of 2002, the Medical Care Availability and Reduction of Error ("MCARE") Act, and then format the data into a standard XML document for batch submission to PA-PSRS. Each facility is responsible for modifying their internal system and conforming to the interface standards published in this document.

1.1 Objectives

The objective of this document is to outline the standard for exchanging data with the Patient Safety Authority's PA-PSRS using a computer-to-computer Data Interface.

1.2 Audience

This document is intended for Pennsylvania medical facilities that intend to submit batched reports to the PSA using the Automated Data Interface feature of PA-PSRS. In particular, this document serves as a guide for the medical facility's IT personnel or representatives in formatting their data into a format that's acceptable to PA-PSRS.

1.3 Content of this Document

The content of this document is grouped into two major topics. The first topic is the *Description of the PA-PSRS Automated Data Interface system* illustrating the sequence of events a facility follows to submit batched report to PA-PSRS. The second topic outlines the procedures and standard format for "*How to Interface with PA-PSRS using the Data Interface system.*"

2 Description of the PA-PSRS Data Interface System

2.1 Data Interface System Diagram

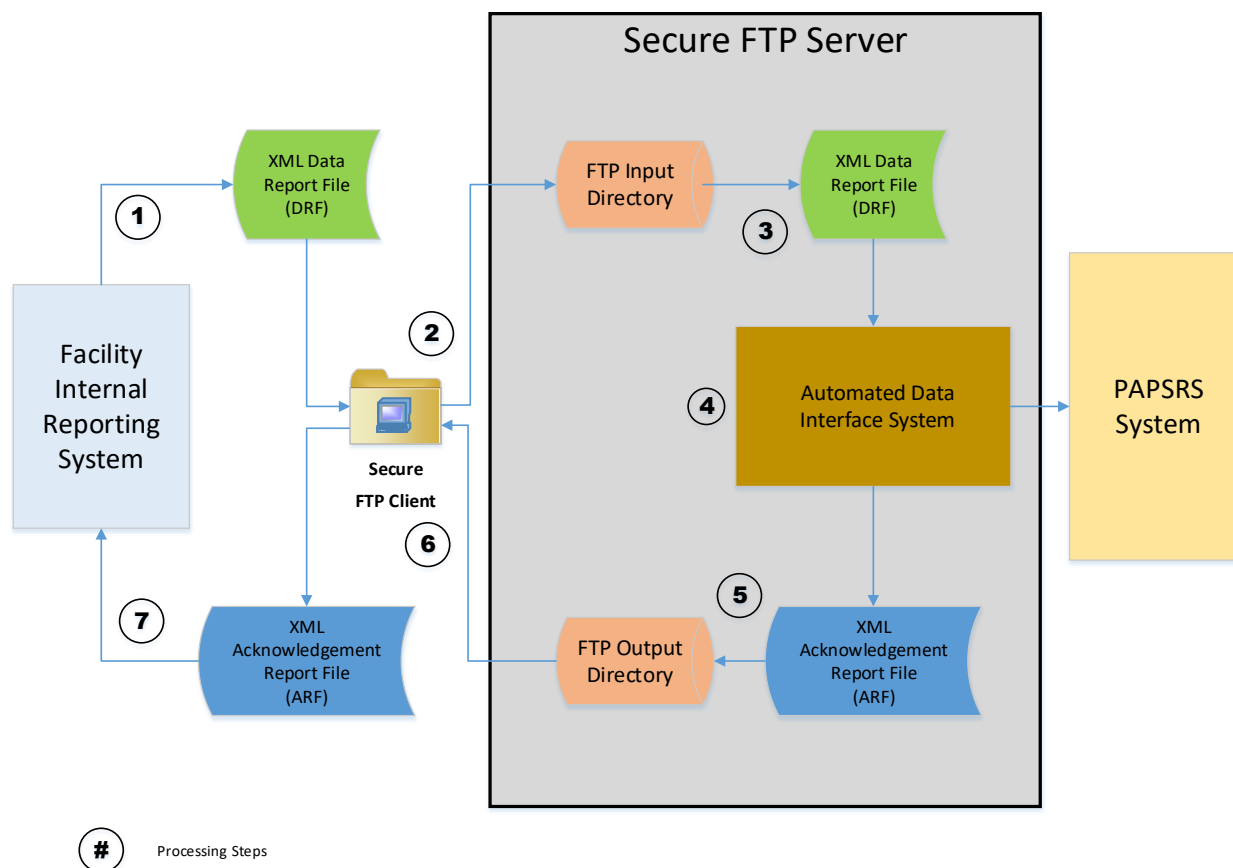


Figure 1 - PA-PSRS Data Interface System Diagram

The diagram above illustrates the components and the system processing flow of the PA-PSRS Data Interface. The Data Interface process is an asynchronous communication between the facility's internal reporting (IR) system and PA-PSRS. Asynchronous communication allows the facility to send batched reports to PA-PSRS and retrieve processing acknowledgement at a later time.

The components that reside within an individual facility are outside the scope of this initiative. That is, the facility is responsible for its own configuration. Since the facility's configuration is unique, the components described in the above diagram are a generic representation of the facility's processes.

2.2 Processes within the Facility Environment

Each facility's internal reporting (IR) system is unique to the facility, and the internal processes described in this document may not represent the true processes at an individual facility. However, the facility's IR system must at minimum be capable of generating a data extract file – "Data Report File (DRF)" that contains batched reports for submission to PA-PSRS. Furthermore, the facility's IR system must be able to process acknowledgements of reports retrieved from PA-PSRS through the Acknowledgement Report File (ARF). The exchange of information between the facility's IR and PA-PSRS will be accomplished using standard file transfer software (FTP). A Secure FTP client software will be made available to the facility to permit a secure transfer of data files between the IR and PA-PSRS.

2.3 Processes within the PA-PSRS Environment

2.3.1 Secured File Transfer Protocol (FTP) Server

The Secured FTP server software runs on the PA-PSRS servers. The Secured FTP server interfaces with the facility's FTP client software to receive the DRF files and allows the facility to download the ARF files.

2.3.2 Automated Data Interface System

The Automated Data Interface system is a set of processes that validates and parses the DRF files received into individual reports. After the reports are parsed and validated, they are submitted into PA-PSRS. Once the reports are submitted, they can be viewed or amended online using the PA-PSRS online reporting system.

The status of submitted reports is communicated back to the facility via an ARF file. The ARF is downloaded by the facility and used to reconcile the reports processed by PA-PSRS.

2.3.3 PA-PSRS

PA-PSRS is the repository of all reports submitted by the facility. In addition, it provides an online interface to allow the facility to submit and amend reports.

The Automated Data Interface system is an enhanced feature of PA-PSRS that allows for submission of batched reports using an unattended computer-to-computer communication.

2.4 Processing Flow of Submitted Reports

This section of the document describes the processing steps that occur when a report is submitted to PA-PSRS via the Data Interface system.

2.4.1 Facility Internal Reporting (IR) system generates the DRF file

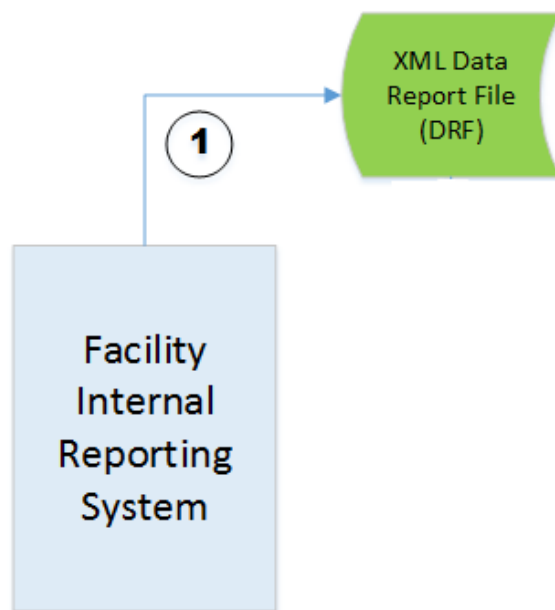


Figure 2 - Generate DRF file

The facility's IR system gathers all reportable events (based on Act 13) since the last transmission and generates an XML Data Report File (DRF). The DRF file is generated on a periodic basis.

Note: Only Act 13 reportable events must be forwarded to PA-PSRS via the interface. Currently, only reports of "NEW" Incidents will be processed. The Data Interface will not accept reports of Serious events, Infrastructure Failure events, or Other events. Also, the Data Interface will not accept amendments to reports already in the system.

2.4.2 Facility transmits the DRF file to PA-PSRS

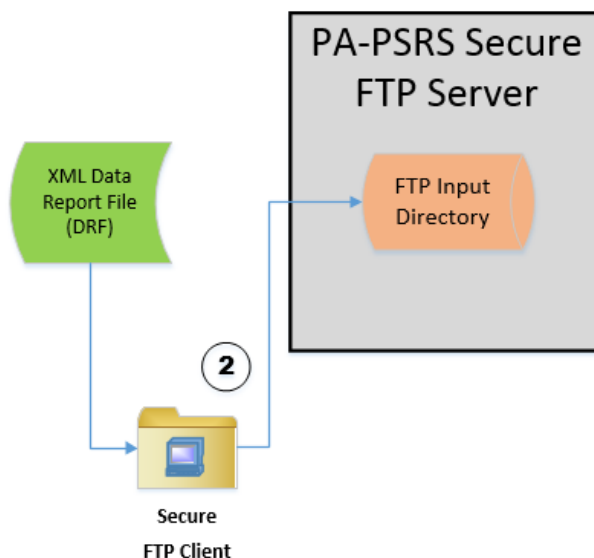


Figure 3 - Transmit DRF file to PA-PSRS

On a scheduled basis, the facility transmits the DRF file to PA-PSRS using secured FTP communication software. For more information on client Secured FTP software, please refer to the *PA-PSRS System WS_FTP Client Software and Configuration*.

2.4.3 PA-PSRS receives the DRF file from the facility

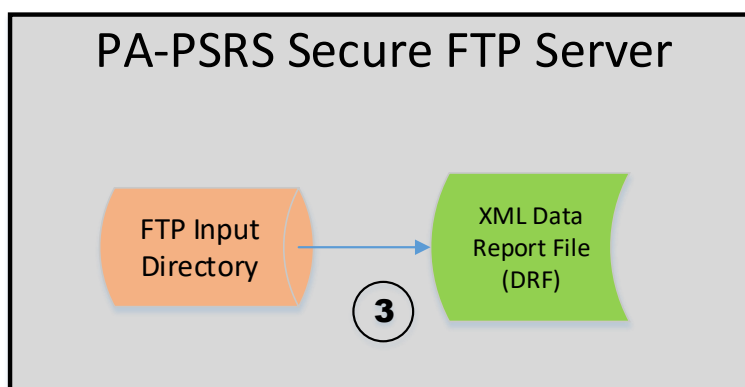


Figure 4 - PA-PSRS receives DRF file

The submission date of each report is the date when the XML DRF file is received by PA-PSRS. The Secured FTP Server is available 24x7, except during regular maintenance periods. Facilities will be notified in advance if the system will be down for maintenance.

2.4.4 DRF file is processed into PA-PSRS

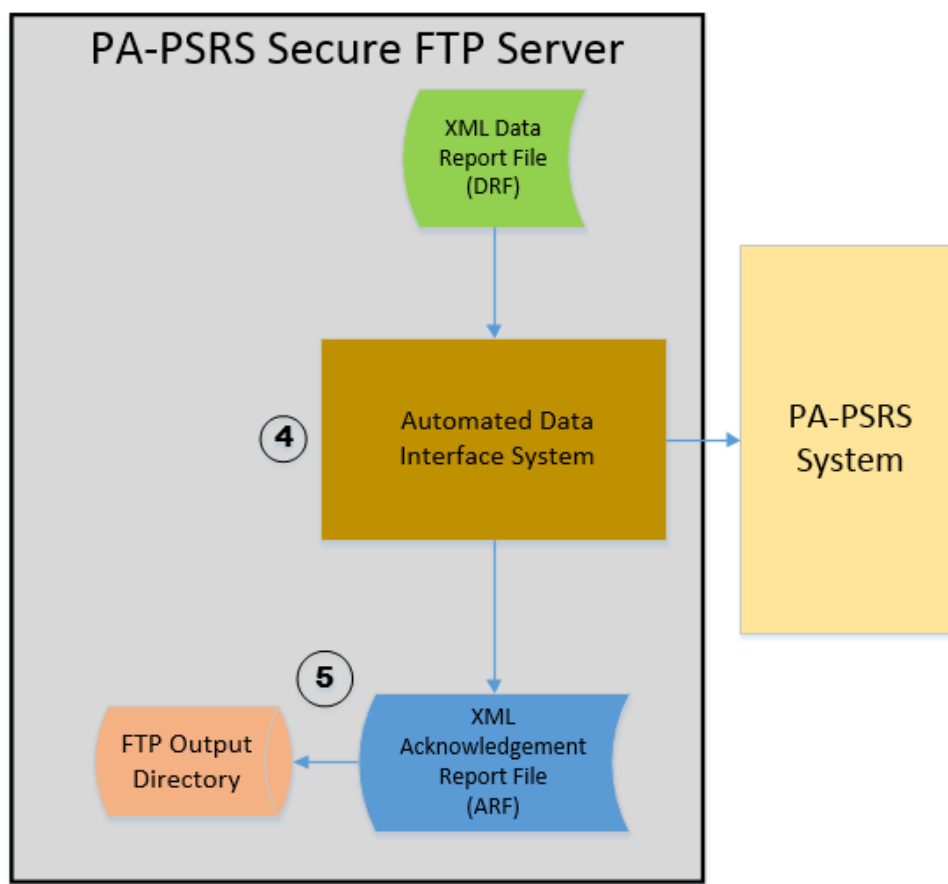


Figure 5 - DRF is processed by PA-PSRS

The Data Interface system scans for new DRF files received from the facility. When new files are identified, the DRF file is parsed into individual reports and validated for conformity with the XML specifications. Reports that pass the validation are submitted into PA-PSRS.

For each report submitted, a response status is generated in an XML format which is grouped and written into the Acknowledgement Report File (ARF). The acknowledgement records are sequenced in the same order they were received in the DRF.

2.4.5 Facility downloads the ARF file from PA-PSRS

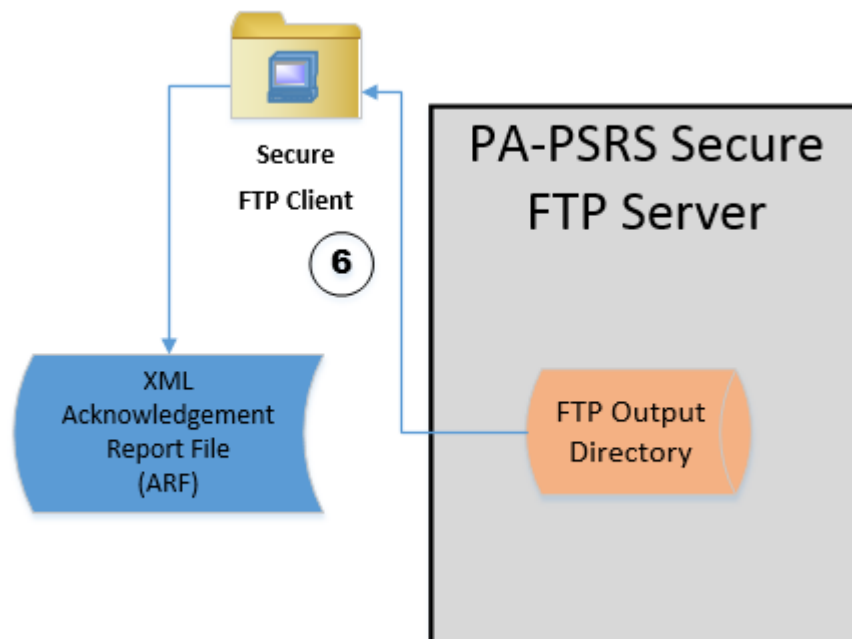


Figure 6 - Facility downloads the ARF

After a batch is processed, an Acknowledgement Report File (ARF) is generated and placed in the OUT directory of the facility. The ARF contains the status of the batch and each report contained within the batch.

Each facility is responsible for downloading and deleting ARF files. Please note that ARF files are not archived. Once a file has been deleted it cannot be recovered.

For a detailed look at the ARF file layout, please refer to the document titled “Part 2 of 3, XML Document Definition”, section 3.

2.4.6 Facility Internal Reporting (IR) system processes the ARF file

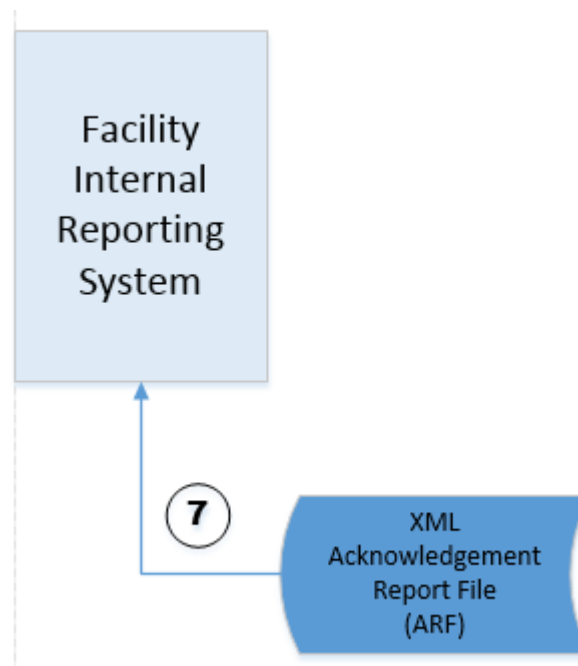


Figure 7 - Facility processes the ARF

The facility may update their IR system with the status of submitted reports received via the ARF file. Contained within the acknowledgement file is the facility's Internal Control Number which may be necessary to reconcile reports. In addition, the acknowledgement file contains the corresponding PA-PSRS report identifier (Report ID).

3 How to Interface with the PA-PSRS

3.1 Conformance Definition

The keywords “MUST,” “MUST NOT,” “REQUIRED,” “SHALL,” “SHALL NOT,” “SHOULD,” “SHOULD NOT,” “RECOMMENDED,” “MAY,” and “OPTIONAL” in this document are to be interpreted as described in Appendix A. These words are capitalized to provide emphasis when they are used.

3.2 System Requirements

1. The facility **MUST** configure their *facility internal reporting system* to generate batched reports, defined as reportable to the Patient Safety Authority under Act 13 of 2002, in an XML file format.
2. Client SFTP or FTPS software that supports client based authentication which is required to support the exchange of PA-PSRS data files. PA-PSRS will support WS_FTP Professional. If need the client software will be provided by the PSA.

3.3 Apply for PA-PSRS Interface Access Requirements

The facility **MUST** complete and submit an application to use the PA-PSRS Data Interface System. The form contains a series of questions to enable the PSA to determine the facility’s readiness to submit reports to PA-PSRS using the Automated Data Interface. Once approved, PSA will contact the facility to initiate the process to submitting reports using the interface.

3.4 System Setup

3.4.1 Install the Client FTP software

The Data Interface has been tested using WS_FTP Professional from Ipswitch Inc. WS_FTP includes a capability to securely transfer data files between the client (facility’s IR) and the server (PA-PSRS). To transfer data files, the WS_FTP client software must be installed on the facility’s server and configured properly. The Patient Safety Authority will provide a copy of the WS_FTP Professional client software to the facility for use with the Automated Data Interface system.

3.5 Security

3.5.1 Data Interface Encryption

Data in transit must be sent via

1. SFTP/SSH (Preferred)

or

2. FTPS with minimum TLS 1.2 encryption

Facilities are encouraged to use FIPS cryptographic standards on clients and software submitting data through the PA-PSRS Data Interface.

3.5.2 Data Interface User-Id and Password

Each facility will be issued a unique User-Id and Password. The User-Id will be used by the facility's internal reporting system to gain access to two facility specific folders on the PA-PSRS system – a folder to send data to PA-PSRS and a folder to receive data from PA-PSRS.

3.6 Interface Conformity Test

A facility must pass the PA-PSRS Interface Conformity Test before interfacing with the PA-PSRS production system. Interface Conformity Testing is a process in which the facility sends several reports representing different reporting scenarios to PA-PSRS.

The Patient Safety Authority will provide the test scenarios. The facility **MUST** enter these reports into their facility's internal reporting system and automatically generate the DRF file for transmission through the PA-PSRS Data Interface.

4 Standards and Naming Conventions

4.1 Lowercase Standardized for Case Sensitivity

PA-PSRS XML element and attribute names are case sensitive. For example, each of the following are considered different names because their case is different:

<submissiontype>

<SubmissionType>

<SUBMISSIONTYPE>

To avoid confusion, all PA-PSRS element and attribute names are standardized on **lowercase**. All facilities must follow the lower case naming convention. In the above example, **<submissiontype>** is the valid name; the other two would be invalid PA-PSRS element and/or attribute names.

4.2 Legal Characters Permissibility

PA-PSRS rules concerning permissible characters on element and attribute names are as follows:

- Starting characters – The names **MUST** begin with an alphabetic letter.
- Valid characters – The names **MAY** include any alphanumeric character, underscores, hyphens, and periods.
- Invalid Characters – The names **MUST NOT** include any white space or any other special character not mentioned in the valid characters list.

4.3 Answers encapsulated with an XML Element

When a facility submits a report using the PA-PSRS online screen, the user is prompted to answer a series of questions using checkboxes, dropdowns lists and text fields. Similarly, when a report is submitted to PA-PSRS through the Data Interface system, an answer to a question is provided through a container called an *element*.

An element is made up of a *start tag*, its *content* and an *end tag*. The *start tag* is enclosed in angle brackets and is given a name that appropriately describes the PA-PSRS question to be answered. The *end tag* is also enclosed in angle brackets but is prefixed with a forward slash (/) after the opening bracket, followed by the same identifier as its companion *start tag*. The *content* is the response to the question. For example, the user selected “**IN**” (Incident) as an answer to Question 1 – Report Submission Type:

<submissiontype>**IN**</submissiontype>

4.4 What is a PA-PSRS Element Attribute

Attributes allow for additional description of the data elements. An *attribute* consists of a name and value bound together in a *name-value* pair. The value **MUST** be enclosed with either single or double quotes. For example, the facility's internal control number (**icn**) for a report is described as an attribute of the report element:

```
<report icn="H23T45">  
</report>
```

4.5 PA-PSRS XML document is Well-Formed

The PA-PSRS XML document contains one or more reports and strictly follows the guidelines of a well-formed XML document.

1. PA-PSRS XML document has a single root document. The “*<papsrs>*” tag is the root of the PA-PSRS XML document

```
<papsrs>  
.  
</papsrs>
```

2. All elements and attribute names have consistent use of **lower case**
3. All non-empty elements have a **closing tag**
4. All empty elements are terminated properly. For example, if a root cause analysis is not provided:

```
<rootcause></rootcause>  
Or  
<rootcause/>  
Or  
{Element is not provided}
```

5. Attribute values are enclosed by **quotation marks**

4.6 Declaring the XML documents

The PA-PSRS XML document has a structure beginning with a root element “<papsrs>.” However, it MUST be preceded by an XML declaration at the top of the file as show below:

```
<?xml version="1.0" encoding="UTF-8" standalone="yes" ?>
<papsrs>
  <facility facid="3475862"></facility>
  <createdate>2007-08-31</createdate>
  <noofreports>1</noofreports>

  <batch batchno="0000001" >
    <report icn="RN0001" type="NEW">
      { Inner elements describing the answer to questions are added
here}

    </report>
    <report icn="RN0002" type="NEW">
      { Inner elements describing the answer to questions are added
here}

    </report>
  </batch>
</papsrs>
```

4.7 Element not required for Optional Questions

If the facility does not provide an answer to an optional question, the user SHOULD NOT provide the element for the answer of the question. A missing element implies that the facility skips the question. For example, the facility does not provide an answer to the detailed question for the **manufacturer** of malfunctioned equipment and the element for the manufacturer is not provided as shown below:

```
<equipmentsupplies>
  <equipmentname>Taxus Stent</equipmentname>
  <modelno>38970-1225</modelno>
  <lotno>714-2400</lotno>
  <removedservice>714-2400</removedservice >
</equipmentsupplies>
```

Note: Due to the file size implication of the XML document, PA-PSRS does not recommend that an empty element be sent to represent a non-response to a question. For example, where a question is left blank, the facility SHOULD NOT transmit the applicable tags as shown here:
<manufacturer></manufacturer>.

4.8 Based on Harm Score, no response is required

If the answer to a question is “Based on Harm Score, no response is required but encouraged” it MUST be provided as an empty element with an attribute of “noresponse.” For example the Team Factors for potential contributing factors:

```
<contributingfactors>
  <teamfactors noresponse="1"></teamfactors>
</contributingfactors>
```

In contrast, if answers are provided:

```
<contributingfactors>
  <teamfactors>
    <commproblem>1</commproblem> ← Communication problem
    <servicechange>1</servicechange> ← Change of service
    <tbd>1</tbd> ← To be determined
  </teamfactors>
</contributingfactors>
```

4.9 XML File Naming Convention

4.9.1 Data Report File (DRF)

The *Data Report File* contains one or more reports for batched submission to PA-PSRS. The facility transmits this file through the PA-PSRS Data Interface system into their assigned IN directory. After PA-PSRS processes this file, it is archived and purged after one week.

The filename of the DRF file is appended with the “_drf” identifier. The file naming convention of the DRF filename is defined as follows:

<YYYYMMDD>-<NNNNNNN>_<drf>.XML

YYYYMMDD – is the date the file was generated by the facility’s internal system. This date does not represent the submission date to PA-PSRS. The submission date is based on the date the file is saved to the facility’s “IN” directory on the PA-PSRS server.

“-“ is a constant character

NNNNNNN – is the 7 digit batched sequence number with leading zeroes. This number is incremented for each batch file sent to PA-PSRS.

“drf” – identifies the file as a data report file for submission.

4.9.2 Acknowledgement Report File (ARF)

The *Acknowledgement Report File* contains an acknowledgment for each report submitted. The PA-PSRS Data Interface system generates this file, and the facility must retrieve the file from their assigned OUT directory.

The filename of the ARF file is the same as the DRF except that an “_arf” identifier is appended to the filename. The file naming convention of the ARF filename is defined as follows:

<YYYYMMDD>-<NNNNNNN>_<arf>.XML

YYYYMMDD – is the date the file was generated by the facility’s IR system. This date does not represent the submission date to PA-PSRS. The submission date is based on the date the file is written in the facility’s “IN” directory on the PA-PSRS server.

“-” is a constant character

NNNNNNN – is the 7 digit batched sequence number with leading zeroes. This number is incremented for each batch file sent to PA-PSRS.

“arf” – identifies the file as a acknowledgement report file.

5 Processing Requirements

5.1 Date of Submission

The date of submission for all the reports contained in the XML document is the date when the DRF file is received by PA-PSRS. The file creation date of the DRF file at the PA-PSRS server is used as the date submitted.

If a report is rejected due to validation errors, the facility can rectify the error and resubmit the report in the next batch submission (or enter it into PA-PSRS manually). The date of submission for the resubmitted report is the received date when the report passes the validation with no errors. The original received date when it was previously rejected is NOT the submission date.

5.2 Transmission of the DRF document

DRF file processing will occur periodically. Therefore, reports transmitted will not immediately appear in the PA-PSRS system. An on-line batch monitoring functionality will allow the facility to track the batch processing results.

5.3 Preventing the submission of Duplicate Reports

Several mechanisms are employed to prevent the submission of duplicate reports. In order to successfully detect duplicate reports, facilities MUST follow the convention and processes laid out in this document.

5.3.1 Detecting Duplicate Batch Files

The batch number assigned to a DRF file SHOULD be incremented by one starting from 0000001. The batch number assigned to the DRF file is compared to the batch number previously submitted. Although batches which do not follow this standard will be accepted and processed, the facility will be warned if the batch number is out of the expected sequence.

If a batch file is detected as a duplicate, an acknowledgement rejecting the entire batch is created. No further validation or processing is performed on the reports contained in the batch file.

The Facility MUST follow the file naming convention of the DRF file. The seven (7) digit batch number SHOULD be continuously incremented by one for each DRF file transmitted to PA-PSRS. The leading zeroes of the batch number MUST NOT be suppressed.

The batch number MUST also be provided as an attribute of the root element <papsrs>. For example, the batch file “**20050507-00000005-DRF.XML**” contains the following root element:
<papsrs batchno=”0000005”>

{Inner elements are defined here}

</papsrs>

5.3.2 Detecting Duplicate Report

The Facility **MUST** provide a unique identifier, the facility Internal Control Number (ICN), for new reports submitted to PA-PSRS. The ICN **SHOULD** be system generated by the facility's internal reporting system and **MUST NOT** be intelligent numbers nor one that directly identifies any individual person or health cases.

The ICN is used by the PSA to programmatically validate if the report was previously submitted. PA-PSRS can accommodate facility internal unique identifiers up to 50 characters long. The valid characters are as follows:

- a-z – lower case alphabets
- A-Z – upper case alphabets
- 0-9 – numbers
- “_” - underline
- “-” dash
- “.” – Period
- “#” - pound sign,

ICN is provided as an attribute of the report element. For example:

```
<report icn="H23T45">  
    {inner child elements are inserted here}  
</report>
```

5.4 Status of Submitted Reports

There are two ways to view the status of submitted batches and reports. Each batch submitted and processed will produce an Acknowledgement Report File (ARF) which details information on each report submitted with the batch. Optionally, the status of each batch and report may be viewed online through the Batch Dashboard from within PA-PSRS.

5.4.1 Acknowledgement Report File (ARF)

For each Data Report File (DRF) submitted and processed, there is an Acknowledgement Report File (ARF). The ARF is formatted as an XML document and contains detailed information on both the batch itself and each report submitted within the batch.

All error messages and warnings are included in this file as well as the process date, time and the corresponding PA-PSRS Report Id. It is also through this file that a facility will be informed if a batch or individual report has been rejected. This comes in the form of error messages contained within the ARF. A batch or report is rejected when a fatal error is encountered.

To reconcile the facilities internal reports with ARF file, the ICN number is included within the report details section.

5.4.2 Batch Upload Dashboard

In addition to the ARF file, PA-PSRS users can view their facility's batch processing results on-line. By clicking *Event Report* then selecting *Interface Dashboard*, a PA-PSRS user can view the current status and processing date of each batch submitted. The user can then drill down further to reveal the Report Id and status of each report contained in the batch. If errors or warnings were encountered, those messages will be displayed under the appropriate Report Id.

If a report was rejected due to a fatal error, the Report Id will be shown as N/A. This indicates that the report was completely rejected and not submitted to PA-PSRS.

■ 3134830		Accepted	Processed	2/17/2006 2:49:34 PM
Report Id	ICN	Status	Process Date	
241327	3134830	Accepted	2/17/2006 2:49:10 PM	
241336	3142322	Accepted	2/17/2006 2:49:10 PM	
241345	3142538	Accepted	2/17/2006 2:49:11 PM	
241354	3160797	Accepted	2/17/2006 2:49:12 PM	
241363	3211180	Accepted	2/17/2006 2:49:13 PM	
241372	3219885	Accepted	2/17/2006 2:49:14 PM	
241381	3257400	Accepted	2/17/2006 2:49:16 PM	
241390	3265467	Accepted	2/17/2006 2:49:19 PM	
241407	3266508	Accepted	2/17/2006 2:49:21 PM	
■ 3092374		Accepted	Processed	2/17/2006 2:50:36 PM
Report Id	ICN	Status	Process Date	
241416	3092374	Accepted	2/17/2006 2:49:23 PM	
241425	3101769	Accepted	2/17/2006 2:49:24 PM	
241434	3102031	Accepted	2/17/2006 2:49:26 PM	
■ N/A	3124075	Rejected	N/A	
		Error Code	Report Error Messages and Warnings	
		V-MED001-F	Validation error encountered on medication error questions. The specific error message is provided under the element <error> The element 'medprescribed' has invalid child element 'medpresroute'. Expected 'medpresfrequency'. An error occurred at file:///C:/Temp/XMLFiles/230201/IN/2006217-3092374_DRF.xml, (348, 2).	
		241443	3130887	Accepted 2/17/2006 2:49:27 PM
		241452	3131187	Accepted 2/17/2006 2:49:28 PM
		241461	3140524	Accepted 2/17/2006 2:49:28 PM
		241470	3140613	Accepted 2/17/2006 2:49:29 PM
		241480	3140631	Accepted 2/17/2006 2:49:30 PM
		241499	3140758	Accepted 2/17/2006 2:49:31 PM
		241505	3140810	Accepted 2/17/2006 2:49:33 PM
		241514	3140856	Accepted 2/17/2006 2:49:34 PM
		241522	3140910	Accepted 2/17/2006 2:49:36 PM

• Figure 8 – Batch Upload Dashboard

6 Part 2 – PA-PSRS Data Interface XML Document Specifications

Please refer to a separate document titled “Part 2 – PA-PSRS Data Interface XML Document Specifications”

7 Part 3 – Appendix

Please refer to a separate document titled “Part 3 –PA-PSRS Data Interface XML Document Specifications - Appendix”